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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/634,656

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Richard L. Dunn

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SCHWEGMAN, LUNDBERG & WOESSNER, P.A.

P.O. BOX 2938

MINNEAPOLIS, MN 55402

EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

08/03/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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request@slwip.com

Office Action Summary	Application No. 10/634,656	Applicant(s) DUNN ET AL.	
	Examiner ANDREW M. GILBERT	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. This office action is in response to the Appeal Brief filed on 2/3/2010 and 1/7/2010.
2. In response the previous rejections have been withdrawn, although the Examiner does not necessarily acquiesce to the Applicant's arguments.
3. Thus, claims 1, 3-25 are pending for examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 5-8, 10-11, 13, 17, 18, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al (5697918). Fischer discloses a coupling syringe system comprising: a first syringe (52) including a first syringe barrel having a first syringe open proximal end and a first syringe distal end, the first syringe further including a first syringe tip with an integral male end portion (54; Fig 5) and a locking ring (55), wherein the locking ring is spaced from an outer surface of the male end portion (55; Fig 5); a first syringe plunger (58) slidably disposed within the first syringe barrel, the first syringe plunger in fluid-tight engagement with an inner surface of the first syringe barrel; a second syringe (12) including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, the second syringe further

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including a second syringe tip (18; Fig 5) with an integral female end portion (18) and one or more exteriorly protruding members (22) adapted to detachably fit the locking ring, wherein the female end portion has an opening defined by an opening wall, which supports the one or more exteriorly protruding members; and a second syringe plunger (14) slidably disposed within the second syringe barrel, the second syringe plunger in fluid-tight engagement with an inner surface of the second syringe barrel, wherein, when the first and second syringes are coupled, the male end portion is received by the opening of the female end portion, and the opening wall and the one or more exteriorly protruding members are received by the spacing between the locking ring and the outer surface of the male end portion, thereby allowing for a single, fluid tight attachment site configured for back and forth transfer of one or more compositions between the first syringe and second syringes (Figs 5-7; the arrangement is fully capable of back/forth transfer). For claim 3 (see Figs 5-7); claim 5 (threads 22, 55); claim 6 (fig 5-7); claims 7-8 (outward flanges (42; 57); claim 10-11 (threads 22, 55; Figs 5-7); claim 13 (wherein either the storage syringe or administration syringe has the dose medicament - Figs 5-7- fully capable of being a drug delivery system); claim 17 (Fig 5); claim 18 (Fig 5; wherein the bulk storage syringe is fully capable of being a single dose syringe - i.e. when the bulk storage has one dose left remaining to transfer to the administration syringe, then the bulk storage syringe is a single dose administration syringe); claim 20 (Fig 5).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 3-14, 17-22, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beller (5984373) in view of Fitoussi et al (5984373).

7. Beller discloses a coupling syringe system comprising: a first syringe (10) including a first syringe barrel having a first syringe open proximal end and a first syringe distal end, the first syringe further including a first syringe tip with an integral male end portion (Fig 4; col 4, lns 29-37); a first syringe plunger (Fig 4) slidably disposed within the first syringe barrel, the first syringe plunger in fluid-tight engagement with an inner surface of the first syringe barrel; a second syringe (6) including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, the second syringe further including a second syringe tip 1) with an integral female end portion (col 4, lns 1-21), wherein the female end portion has an opening defined by an opening wall, which supports the one or more exteriorly protruding members; and a second syringe plunger (Fig 4) slidably disposed within the second syringe barrel, the second syringe plunger in fluid-tight engagement with an inner surface of the second syringe barrel, wherein, when the first and second syringes are coupled, the male end portion is received by the opening of the female end portion, and the opening wall and the one or more exteriorly protruding members are received by the spacing between the

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locking ring and the outer surface of the male end portion, thereby allowing for a single, fluid tight attachment site configured for back and forth transfer of one or more compositions between the first syringe and second syringes (Fig 4; Summary). Further disclosing the syringes being the same size (Fig 4) and one syringe having contrast medium (Summary) and the other syringe having air – acting as a drug administration system (Summary); a needle cannula and hub (col 3, lns 1-3).

8. However, Beller discloses the invention substantially as claimed except for expressly disclosing a locking ring rotatable around the male luer for attaching to threads on a female luer. Fitoussie et al teaches that it is known to have a locking ring rotatable around the male luer for attaching to threads on a female luer (Figs 1-3b) for the purpose of providing a fluid tight connection between two different medical devices. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the male/female connection as taught by Beller with the locking ring and threads as taught by Fitoussie et al for the purpose of providing a fluid tight connection between two different medical devices.

9. Claims 15-16, 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beller in view of Fitoussie et al in further view of Cha et al (5701717). Beller and Fitoussie disclose the invention substantially as claimed except for expressly disclosing compositions comprising leuprolide acetate, poly(DL-lactide-co-glycolide) and N-methyl-z-pyrrolidone to be mixed for subsequent administration to a patient. . Cha suggests the mixing of leuprolide acetate, poly(DL-lactide-co- glycolide) and N-methyl-z-pyrrolidone to make a composition for injection into a patient column 1, line 65 - column

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2, line 17 and column 2, line 45 - column 3, line 35). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Cha in the device of Beller and Fitoussie in order to achieve a mixing system that quickly and thoroughly mixes a desired composition where the mixed composition is contained in a syringe for patient injection for injecting a therapeutic agent in a biodegradable matrix with solvent present for ease of administration. Cha suggests the desirability of mixing these components for patient treatment.

Response to Arguments

2. Applicant's arguments with respect to claims 1 and 3-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 Form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767